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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,727	12/05/2005	Farid Vaghefi	34074.00022/07.1005	4206

61214 7590 02/01/2011

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EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
02/01/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@foxrothschild.com

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/528,727	VAGHEFI ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds Draper	1614	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 January 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,4,5,9,11,24 and 40*.
   Claim(s) withdrawn from consideration: *12-23 and 27-39*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/Leslie A. Royds Draper/
Primary Examiner, Art Unit 1614

Continuation of 5. Applicant's reply has overcome the following rejection(s): the objection of claim 9; the rejection of claims 7 and 24 under 35 USC 112p2; the rejection of claims 4-5 and 40 under 35 USC 112p1 regarding the limitation directed to a 'viscoelastic polymer'; and the rejection of claim 7 under 35 USC 103(a).

Continuation of 11. does NOT place the application in condition for allowance because:

Applicant requests reconsideration of the instant rejection under 35 USC 112p1, stating that the proper analysis of adequate written description requires consideration of actual reduction to practice, disclosure of drawings or structural chemical formulas, and sufficient relevant identifying characteristics, such as complete structure, partial structure, physical and/or chemical properties, functional characteristics when coupled with known or disclosed correlation between function and structure, method of making the claimed invention, level of skill and knowledge in the art and predictability in the art. Applicant asserts that the rejection amounts to a general allegation that the language of "opioid agonist" is broad and provides no analysis and/or any evidence suggesting that any specific opioid agonist would not work in the frameword of the present invention. Applicant references p.7, l.7-9 and p.7, l.7-p.8, l.15 for disclosure of opioid agonists.

These arguments are unpersuasive. Applicant appears to have misunderstood the basis of the instant rejection. This is a new matter rejection, not whether Applicant has provided a representative number of species of the genus of "opioid agonists". The issue at hand is that Applicant has only enumerated specific species of opioid agonists (i.e., morphine, fentanyl, etc.) but has never disclosed per se the much broader concept of using an "opioid agonist" in the instant invention. The disclosure of particular species of agonists in the specification and claims as originally filed does not provide adequate disclosure to then claim later, AFTER the original filing, the much broader concept that ANY opioid agonist may be used. The disclosure of the generic concept of the use of any opioid agonist is not present in the specification and claims as originally filed for the reasons clearly disclosed in the final rejection. The Examiner makes no assertions as to whether any such agonist may or may not work in the so-called "framework" of the instant invention, but rather has assessed the disclosure as originally filed to determine whether Applicant described possession of the concept of using ANY opioid agonist and not just the specifically enumerated species described in the specification as originally filed, which he has not. Applicant has failed to point to where the specification supports the much broader concept of using any opioid agonist in the instant invention. Absent such disclosure, the new matter rejection on these grounds remains proper for the reasons of record.

Applicant further argues that p.3, l.8-10 supports the limitation directed to the composition not including an antagonist of the water soluble compound capable of abuse. This is unpersuasive because this disclosure is a statement regarding what is or is not disclosed in the prior art and makes no reference to what the instant invention does or does not contain. The fact remains that the specification and/or claims as originally filed are silent as to whether such an antagonist is or is not permitted as a component of the composition for the reasons of record. The rejection is maintained for the reasons of record.

Applicant additionally requests reconsideration of the instant rejection under 35 USC 103(a), stating that the Examiner has ignored the limitation directed to the fact that each particle of a water soluble compound is wetted with a coating of the matrix material and that the composition comprises a plurality of microspheres and each microsphere has the composition set forth in (i) and (ii) of instant claim 1. These arguments are unpersuasive. Cain et al. teaches a tablet comprising a matrix material that is, inter alia, carnauba wax (i.e., the water-insoluble matrix material as defined in instant claim 40) and a therapeutic agent, such as dihydrocodeinone bitartrate, wherein the matrix is an aggregate of carnauba wax in which are embedded a mixture of the active ingredient and filler, wherein Cain et al. specifically states that the tablet matrix forms a skeleton in the spaces of which the filler and active ingredient particles are distributed in mixed intimate relation (i.e., the particles are embedded within and, thus, coated by, the matrix material). Furthermore, Cain et al. clearly discloses the microspherical nature of the plurality of particles contained inside the composition. It is unclear exactly what elements Applicant alleges are not taught by the reference and how the instant claims avoid the teachings of Cain et al. by comparing the instant invention to the prior art. Such an argument is an assertion of patentable novelty and nonobviousness without clearly setting forth what Applicant believes is not met by the cited reference. Accordingly, the rejection remains proper for the reasons set forth at p.9-12 of the final rejection dated October 20, 2010.

For these reasons supra, and those previously made of record in the final rejection dated October 20, 2010, the rejections remain proper and are herein maintained.

/Leslie A. Royds Draper/
Primary Examiner, Art Unit 1614